Bobrowski, Paul

Serial No.: Atty. Docket No.:

10/674,587 PHMC0745-021

Amendment dated 9/27/2005

Reply to Office Action of June 6, 2005

Art Group:

Examiner:

1654

Susan B. McCormick-Ewoldt

### **REMARKS/ARGUMENTS**

- 1. Claims 1-10 remain in this application. Claim 3 has been canceled. Claims 11-19 have been withdrawn as the result of an earlier restriction requirement. Applicant retains the right to present claims 11-19 in a divisional or continuation application. Claims 20 - 29 are new.
- 2. The Examiner objected to the comma in claim 6. The Applicant has amended the claim accordingly.

# Claim Rejections - 35 U.S.C. § 112 - first paragraph

- 3. The Examiner rejected claim 1 under 35 U.S.C. §112, first paragraph. The Examiner has alleged that the disclosed embodiment of the species Croton is not representative of all the plants of genus Euphorbacea and that Applicant has not enabled claims to the entire genus.
- 4. The Applicant has amended claim 1 to recite the species Croton reflecting the embodiment disclosed in the specification. New claim 20 also recites the species Croton.

## Claim Rejections - 35 U.S.C. § 112 - second paragraph

- 5. The Examiner rejected claims 1-10 under 35 U.S.C §112, second paragraph, alleging that said claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.
- 6. The Examiner rejected claim 1 alleging that "the lipophilic components" in line The Applicant asserts that the context of the 1 lacks antecedent basis. claimed recitation would be clear to one of ordinary skill in the art. One of ordinary skill would recognize that Croton species plants inherently comprise both lipophilic and hydrophilic components. Still, the Applicant has amended the claim according to the Examiner's suggestion, but no change to claim scope has been affected.

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- 7. The Examiner also alleges that claim 1 appears to have no step for hydrophilic constituents and lipophilic components after evaporation and that the extracted lipophilic components are still with the hydrophilic constituents.
- 8. The Applicant asserts that the claimed invention would be clear to one of ordinary skill in the art. One of ordinary skill would recognize that the Applicant is separating and retaining the lipophilic components in the organic layer. Applicant has amended the claim to express a recitation of the step of "separating" the organic layer from the hydrophilic layer for further processing (i.e. evaporation).
- 9. The Examiner also alleges that in claim 1, lines 6 and 7, the term "substantially" is indefinite because it is not clear what is encompassed by this term.
- 10. The Applicant alleges that the meaning of the term "substantially" would be clear to one of ordinary skill in the art. Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 65 USPQ2d 1051(Fed. Cir. 2002) (Writing that when "substantially" serves reasonably to describe the subject matter so that it would be understood by a person of ordinary skill and to distinguish from the prior art, it is not indefinite.) Organic extractions are well known in the art .the imposition of organic solvent upon a substance comprised at least partially of organic components will dissolve the more non-polar lipophilic constituents whereas the polar constituents will be largely unaffected by the organic solvent. No prior art reference discloses that the organic lipophilic components of Croton plant can be separated (i.e. extracted) from the aqueous hydrophilic components to yield a bioactive substance with desirable properties. Thus, relative to the prior art, any separation and retention of the lipophilic and hydrophilic components caused by an organic extraction is substantial.

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11. Finally, the Examiner objected because the Applicant has claimed that its process includes the step of "evaporating the organic layer", which is allegedly in conflict with the Applicant's goal.

- 12. The Applicant again alleges that the meaning of this step would be clear to one of ordinary skill given the Applicant's goal of creating an organic extraction and the context of the claim. It would be clear to one of ordinary skill that the Applicant's invention intends to evaporate the organic solvent to retain the lipophilic constituents.
- 13. The Examiner also alleges that in claim 2, the recitation "at least partially" is indefinite. The claim has been amended.

## Claim Rejections - 35 U.S.C. § 103

- 14. The Examiner has rejected claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tempesta (US 5,494,611) and Nkiliza (US 5,928,646).
- 15. The Examiner alleges that Tempesta (US 5,494,611) discloses: extracting proanthocyanidins from Croton species (column 8, lines 25-27); subjecting Croton latex to partitioning by ethyl acetate and water (column 10, lines 38-39); extraction with isopropanol and evaporation to dryness by in vacuo (column 13, lines 45-56); and a wavelength range between from 202 nm to 600 nm (column 1-3). The Examiner admits that Tempesta does not disclose using a drying agent such as magnesium sulfate or sodium sulfate; but alleges that Nkiliza (US 5,928,646) discloses extracting proanthocyanidins using methanol ethyl acetate and drying agents such sodium sulphate and magnesium sulphate (column 1, lines 12-14; column 3, lines 4-10).
- 16. Based on the above, the Examiner alleges that a person of ordinary skill in the art would reasonably expect that the solvents and drying agents used in

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the proanthocyanidin extraction of Nkiliza could be used in the proanthocyanidin extraction of Tempesta; and that based on this reasonable expectation of success, a person or ordinary skill in the art would be motivated to make these modifications to Tempesta.

- 17. The Applicant respectfully disagrees that the Tempesta can be used to obviate his invention, if as the Examiner alleges, Tempesta discloses extracting and concentrating proanthocyanidins from Croton species. The Applicant has disclosed and claimed a process for concentrating the organic lipophilic constituents from Croton species - not the aqueous hydrophilic components, which comprises the proanthocyanidins targeted and desired by Tempesta. A proposed modification of a reference cannot materially alter a principle of operation or end-result of the reference. See In re Gordon, 733 F.2d 900 (Fed. Cir. 1984). Thus, Tempesta teaches away from the Applicant's invention. Accordingly, rather than a "reasonable expectation of success", the person of ordinary skill would be guaranteed NOT to arrive at the Applicants' claimed process given the motivation, suggestions, and teachings of Tempesta.
- 18. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

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Respectfully submitted,

Ellis & Venable

Date: September 27, 2005

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#### **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage paid, in an envelope addressed to:

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on September 27, 2005

Michael F. Campillo